<u>REMARKS</u>

This Response responds to the non-final Office Action, mailed March 29, 2004. Claims 51-63 are pending. Reconsideration of the present application in view of the following remarks is respectfully requested.

I. THE REJECTIONS UNDER 35 U.S.C. § 112

Claims 52-55 and 62 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner alleged deficiencies with respect to two claim limitations.

First, the Examiner contended that there was insufficient written description for the limitation of independent claim 53, and dependent claims 54 and 55, that "the capture ring [has] an aperture greater than the first diameter but smaller than the second diameter." In claim 53, the "first diameter" is a diameter of a first portion of a guide wire and the "second diameter" is a diameter of a distal region of the guide wire. The "capture ring," which is a part of the filter element, has an aperture greater than the first diameter so the capture ring can rotate and distally translate along this portion of the guide wire. In addition, the "capture ring" has an aperture smaller than the second diameter of a distal region of the guide wire such that the capture ring cannot distally translate beyond that distal region.

For ease in understanding Applicants' support for the challenged phrase, Applicants refer to Figures 17-20 of the captioned application. The "distal stop" and "capture ring" recited in claim 53 refer to, for example, the "distal docking member" 216 and "distal cone" 232, respectively, of Figures 17-20. As shown, cone 232 is coupled to a distal end of protection device (filter device) 230. Cone 232 is formed of a rigid member having a *distal opening (not shown) sized for insertion of guide wire 210 therethrough* (p. 18, Il. 27-30). This alone shows that the aperture of cone 232 is greater than the diameter of the guide wire. In addition, the application describes that the filter device 230 is mounted on the guide wire 212 by inserting the guide wire *through* an opening in cone 232 and advancing the filter device over the guide wire 212 (p. 19, Il.1-3). This also demonstrates that the distal cone 232 has an aperture greater than the diameter of the guide wire, *i.e.*, greater than the "first diameter."

The docking member 216 is located on a distal region 210 of the guide wire 212. Docking member 216 is *rigidly coupled* to (p. 18, ll. 3-8) or permanently formed on (p. 18, ll. 13-14) the distal region 210 of the guide wire 212. Such rigid coupling on a distal region of

the guide wire constitutes a "stop" that limits translation of the cone 232 in a distal direction. That being so, and as shown in Figure 18, the docking member 216 on the distal region of the guide wire *necessarily* has a diameter greater than the aperture of the cone 232 (or it would not stop translation of the cone). Moreover, cone 232 includes a locking ring 242 extending about an outer perimeter of cone 232 (p. 18, ll. 30-31). Locking ring 242 is sized for insertion into grove 222 of docking member 216 (p. 18, ll. 31-33). Clearly, the diameter of docking member 216 must be greater than the diameter of cone 232.

Thus, the specification has written description for a capture ring having an aperture greater than the diameter of a first portion of the guide wire and smaller than the diameter of a second portion on a distal region of the guide wire.

Second, the Examiner contended that there was insufficient written description for the limitation of independent claims 52 and 62 that "retracting the guide wire . . . causes the distal stop to abut against the filter element."

At the outset, Applicants point out that claim 52 recites "retraction of the guide wire ... causes the stop to abut against the *capture ring*." As described in the application, the capture ring (or cone 232) is part of the filter element (or protection device 230).

As established above, the docking member 216 on a distal region of the guide wire is *fixedly attached* to the guide wire 212 and has a diameter greater than that of the aperture of cone 232. That being so, retraction of the guide wire 212 (*i.e.*, pulling the guide wire in the proximal direction through cone 232) would *necessarily* cause the docking member 216 to abut against, or contact, cone 232. Applicants note that there is no requirement in claim 52 that the recited retraction of the guide wire be done in order to collapse the filter element. Claim 52 merely states that retraction of the guide wire (for whatever reason) in a proximal direction causes the stop (or docking member 216) to abut against the capture ring (or cone 232), and this would necessarily happen with Applicants' device of Figure 18.

Similarly, claim 62 recites "retracting the guide wire . . . to cause the distal stop to abut against the filter element." As noted with respect to claim 52, retraction of the guide wire 212 for whatever reason necessarily causes the docking member 216 to abut against the cone 232 (which is part of the filter device 230). There is no requirement in claim 62 that the guide wire be retracted for the purpose of collapsing the filter element.

Applicants respectfully request that the rejection of claims 52-55 and 62 under Section 112, first paragraph, be withdrawn.

II. THE REJECTIONS UNDER 35 U.S.C. § 102(e)

Claims 51, 56-61 and 63 have been rejected under 35 U.S.C. § 102(e) as anticipated by Ladd, U.S. Patent No. 6,059,814. As demonstrated below, the Ladd patent fails to satisfy every limitation of Applicants' rejected claims.

The Examiner stated:

As to claims 51, 59, and 60, Ladd discloses in figure 1, a stop (38) disposed on the distal region of the guide wire (28); a filter sac (40) connected to a capture ring (44), wherein the capture ring (44) disposed for translation on the guide wire (28) (see col. 5, lines 57-59); wherein the stop (38) is limiting the translation of the capture ring (44) in a distal direction (see col. 6, line 20-21); wherein the filter comprising a self-expanding strut (46); and wherein the rotation of the filter or distal translation of the guide wire (28) relative to the capture ring (44) does not displace the filter sac (40).

As to claims 56-58, 61, and 63, Ladd discloses in figure 1 and (col. 6, lines 9-65), the method of providing a stop (38) disposed on the distal region of the guide wire (28); a filter sac (40) connected to a capture ring (44), wherein the capture ring (44) disposed for translation on the guide wire (28) (see col. 5, lines 57-59); wherein the stop (38) is limiting the translation of the capture ring (44) in a distal direction (see col. 6, line 20-21); wherein the filter comprising a self-expanding strut (46); wherein the rotation of the filter or distal translation of the guide wire (28) relative to the capture ring (44) does not displace the filter sac (40); and further providing a delivery sheath (or catheter) (18) for compressing the filter (40) to a contracted state.

Office Action, p. 3 (emphasis added).

There are fundamental differences between the device described in the Ladd patent and Applicants' claimed invention. Referring to Figure 1 of the Ladd patent, the device described has a filter sac (40) attached to a hollow rod (28) that is capable of rotation on and distal translation over the guide wire (36). On the hollow rod (28) there is a stop (38) distal to the filter sac (40); there is no distal stop on the guide wire (36).

Specifically, and citing to the specification, the Ladd patent describes the guide wire as element (36) (see, e.g., col. 4, l. 63), not element (28) as stated by the Examiner. Element (28) is a hollow rod that slides over the guide wire (36) (col. 4, ll. 57-61). The guide wire (36) is housed within the lumen (32) of the hollow rod (28) (col. 4, ll. 63-64). The rod (28) includes a stop (38) mounted on its outer wall (30) (col. 4, ll. 64-65); the stop (38) is not mounted on the guide wire (36). Thus, in considering the Ladd patent, the Examiner has mistaken the hollow rod (28) for the guide wire (36) and incorrectly stated that the stop (38) is on the guide wire (36) when, in fact, it is on the hollow rod (28).

All of Applicants' claims, on the other hand, are directed to a device in which the distal stop is on the guide wire:

<u>Claims 51-52</u>: "a guide wire having a distal region and a stop on the distal region"

<u>Claims 53-55</u>: "a guide wire having a first portion having a first diameter and a distal region having a second diameter greater than the first diameter" and "the capture ring having an aperture greater than the first diameter but smaller than the second diameter"

Claims 56-58: "a guide wire having a distal region including a stop"

<u>Claims 59-60</u>: "a guide wire having a distal region" and "a distal stop disposed on the distal region distal to the filter element"

<u>Claims 61-63</u>: "a guide wire having a distal region including a distal stop" See also the discussion of Applicants' Figure 17 and the specification at page 18, lines 3-8:

Guide wire 210 is formed of an elongated wire 212, preferably having a spring coil tip 214, and a protective device docking member 216 coupled to a distal portion of wire 212, as illustrated in FIG. 17. Docking member 216 is rigidly coupled to wire 212....

As can readily be understood from Applicants' disclosure and as recited in Applicants' claims, the distal stop (*i.e.*, docking member 216) is rigidly attached directly to the guide wire, which is clearly different from that device of the Ladd patent. For this reason alone, the Ladd patent does not anticipate any of Applicants' claims.

Moreover, the Examiner incorrectly characterized the device of the Ladd patent in the rejection by stating: "wherein the rotation of the filter or distal translation of the guide wire (28) relative to the capture ring (44) does not displace the filter sac (40)."

Importantly, the Ladd patent describes the filter as "fixedly connected" to the hollow rod (28):

Filter assembly 40 comprises a proximal ring connector 42 and a distal ring connector 44 located between proximal connector 42 and stop 38. . . . Proximal ring 42 is fixedly connected to outer wall 30 [of rod 28] while distal ring 44 is free to slide longitudinally along the outer wall of rod 28.

Ladd patent, col. 5, lines 1-7.

Since the proximal ring connector 42 is fixedly connected to the outer wall 30 of hollow rod 28, rotation or distal translation of hollow rod 28 would cause displacement of the filter sac, which is contrary to the characterization of the rejection. For this additional reason, the device of the Ladd patent does not anticipate any of Applicants' claims.

Applicants respectfully request that the rejection under 35 U.S.C. § 102(e) be withdrawn.

III. CONCLUSION

In light of the above remarks, Applicants respectfully request that the Examiner reconsider this application and allow all claims.

Applicants note that their first request for an interference with U.S. Patent No. 6,179,859 was filed 2½ years ago (January 29, 2002) and their second request for an interference with application Serial No. 09/774,197, now U.S. Patent No. 6,468,291, was filed two years ago (July 30, 2002). Since examination of applications in which an interference with a patent has been requested "shall be conducted with special dispatch" (37 C.F.R. § 1.607(b)), Applicants respectfully request prompt action on this application.

The Examiner is invited to call the undersigned attorney at (212) 326-3939, if a telephone call could help resolve any remaining items.

Date:

July 14, 2004

Respectfully submitted,

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